

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

7943M

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.
PCT/US00/17177INTERNATIONAL FILING DATE
22 June 2000 (22.06.00)PRIORITY DATE CLAIMED
12 November 1999 (11.99)TITLE OF INVENTION
Chewing Gum CompositionsAPPLICANT(S) FOR DO/EO/US
DAY, Trevor Neil et al

JC07 Rec'd PCT/PTO

09 MAY 2001

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(I).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application was filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. To 16. Below concern document(s) or information included:


11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☒ A change of power of attorney and/or address letter.
16. ☐ Other items or information:

"Express Mail" mailing label number EL837715339USDate of Deposit 09 May 2001

I hereby certify that this paper/fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to The Assistant Commissioner of Patents, Washington, D.C. 20231

James Huerter
Administrator Mailing Application

Signature

U.S. APPLICATION NO. 09/831462		INTERNATIONAL APPLICATION NO. PCT/US00/17177		ATTORNEY'S DOCKET NUMBER 7943M	
				CALCULATIONS PTO USE ONLY	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$670	
Surcharge of \$130.00 for furnishing the oath or declaration later than [] 20 [x] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	20 =	0	x \$22.00	\$	
Independent Claims	3 =	0	x \$78.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			\$250.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	
Processing fee of \$130.00 for furnishing the English translation later than [] 20 [] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$0	
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28,3.31). \$40.00 per property +				\$0	
TOTAL FEES ENCLOSED =				\$	
				Amount to be refunded	s
				charged	s
<p>a. [] A check in the amount of \$ ____ to cover the above fees is enclosed.</p> <p>b. [x] Please charge my Deposit Account No. <u>16-2480</u> in the amount of \$ ____ to cover the above fees.</p> <p style="padding-left: 40px;">A duplicate copy of this sheet is enclosed.</p> <p>c. [x] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>16-2480</u>. A duplicate copy of this sheet is enclosed.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p>					
Emelyn L. Hiland Patent Division The Procter & Gamble Company Health Care Research Center 8340 Mason-Montgomery Road Mason, Ohio 45040			 Signature <u>T. David Reed</u> Name <u>32,931</u> Registration Number		

RECEIVED BY MAIL

09/831462

USPTO Patent PCT/US 09 MAY 2001

Case 7943M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Matter of:

U.S. National Phase Entry

Under 35 USC § 371 from

the International Application of :

DAY, Trevor et al :

Int'l Application No. PCT/US00/17177 :

Filed in the RO/US on 22 June 2000 :

Entitled: Chewing Gum Compositions

PRELIMINARY AMENDMENT UNDER 37 CFR § 1.112

Assistant Commissioner for Patents

Washington, D.C. 20231

Dear Sir:

Prior to Examination and computation of the fees for entering the captioned International Application into the U.S. National Phase, please preliminarily amend the above-identified application as follows and consider the following Remarks.

AMENDMENTS

IN THE SPECIFICATION:

Please insert the following paragraph at Page 1, Line 7 immediately before the section "BACKGROUND OF THE INVENTION".

-- CROSS-REFERENCE

This application claims the benefit of US Provisional Application 60/165,351 filed November 12, 1999 and US Provisional Application 60/180,352 filed February 4, 2000. --

IN THE CLAIMS:

Please cancel Claims 18-25.

Please add the following new Claims 18-40.

18. (New) A composition according to Claim 17 which comprises from about 0.5% to about 30%, by weight, of particulate polyphosphate.

19. (New) A composition according to Claim 17 which comprises from about 1% to about 15%, by weight, of particulate polyphosphate.

20. (New) A composition according to Claim 17 which comprises from about 5% to about 12%, by weight, of particulate polyphosphate.
21. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it passes through a 1mm mesh.
22. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it passes through a 0.8mm mesh.
23. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it passes through 0.5mm mesh.
24. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it passes through a 0.4mm mesh.
25. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it is retained by a 0.112mm mesh.
26. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it is retained by a 0.16mm mesh.
27. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it is retained by a 0.18mm mesh.
28. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a particle size such that it is retained by a 0.2mm mesh.
29. (New) A composition according to Claim 17 wherein the particulate polyphosphate is sodium polyphosphate with an average chain length of from about 10 to about 30.
30. (New) A composition according to Claim 17 wherein the particulate polyphosphate is sodium polyphosphate with an average chain length of from about 15 to 25.
31. (New) A composition according to Claim 17 wherein the particulate polyphosphate is sodium polyphosphate with an average chain length of from about 21 to about 23.
32. (New) A composition according to Claim 17 wherein the particulate polyphosphate has an aqueous solubility of at least about 8g per 100ml at 25°C.
33. (New) A composition according to Claim 17 wherein the particulate polyphosphate has an aqueous solubility of at least about 10g per 100ml at 25°C.
34. (New) A composition according to Claim 17 wherein the particulate polyphosphate has an aqueous solubility of at least about 15g per 100ml at 25°C.
35. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a hardness of greater than 1 when measured using the Mohs hardness scale.
36. (New) A composition according to Claim 17 wherein the particulate polyphosphate has a hardness of 2 or greater when measured using the Mohs hardness scale.

37. (New) A composition according to Claim 17 wherein the particulate polyphosphate is dispersed throughout the chewing gum composition.
38. (New) A composition according to Claim 17 wherein the weight ratio of gum to particulate polyphosphate is in the range from about 10:1 to about 1:10.
39. (New) A composition according to Claim 17 wherein the weight ratio of gum to particulate polyphosphate is in the range from about 5:1 to about 1:5.
40. (New) A composition according to Claim 17 wherein the weight ratio of gum to particulate polyphosphate is in the range from about 5:1 to about 1:1.

REMARKS

Attached hereto is a marked-up version of the changes made to Page 1 of the specification and claims by the current amendment. The Specification is amended to indicate the priority claims. Original Claims 18-25 are canceled and presented as new Claims 18-40. The attached page is captioned "Version With Markings to Show Changes Made".

Respectfully submitted,

By



T. David Reed
Agent for Applicants
Registration No. 32,931

25 April 2001
5299 Spring Grove Avenue
Cincinnati, Ohio 45217-1087
Phone: (513) 627-7025
FAX: (513) 627-6333

Year	1982/1983	1983/1984	1984/1985	1985/1986	1986/1987	1987/1988	1988/1989	1989/1990	1990/1991	1991/1992	1992/1993	1993/1994	1994/1995	1995/1996	1996/1997	1997/1998	1998/1999	1999/2000	2000/2001	2001/2002	2002/2003	2003/2004	2004/2005	2005/2006	2006/2007	2007/2008	2008/2009	2009/2010	2010/2011	2011/2012	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021	2021/2022	2022/2023	2023/2024	2024/2025	2025/2026	2026/2027	2027/2028	2028/2029	2029/2030	2030/2031	2031/2032	2032/2033	2033/2034	2034/2035	2035/2036	2036/2037	2037/2038	2038/2039	2039/2040	2040/2041	2041/2042	2042/2043	2043/2044	2044/2045	2045/2046	2046/2047	2047/2048	2048/2049	2049/2050	2050/2051	2051/2052	2052/2053	2053/2054	2054/2055	2055/2056	2056/2057	2057/2058	2058/2059	2059/2060	2060/2061	2061/2062	2062/2063	2063/2064	2064/2065	2065/2066	2066/2067	2067/2068	2068/2069	2069/2070	2070/2071	2071/2072	2072/2073	2073/2074	2074/2075	2075/2076	2076/2077	2077/2078	2078/2079	2079/2080	2080/2081	2081/2082	2082/2083	2083/2084	2084/2085	2085/2086	2086/2087	2087/2088	2088/2089	2089/2090	2090/2091	2091/2092	2092/2093	2093/2094	2094/2095	2095/2096	2096/2097	2097/2098	2098/2099	2099/2100	2100/2101	2101/2102	2102/2103	2103/2104	2104/2105	2105/2106	2106/2107	2107/2108	2108/2109	2109/2110	2110/2111	2111/2112	2112/2113	2113/2114	2114/2115	2115/2116	2116/2117	2117/2118	2118/2119	2119/2120	2120/2121	2121/2122	2122/2123	2123/2124	2124/2125	2125/2126	2126/2127	2127/2128	2128/2129	2129/2130	2130/2131	2131/2132	2132/2133	2133/2134	2134/2135	2135/2136	2136/2137	2137/2138	2138/2139	2139/2140	2140/2141	2141/2142	2142/2143	2143/2144	2144/2145	2145/2146	2146/2147	2147/2148	2148/2149	2149/2150	2150/2151	2151/2152	2152/2153	2153/2154	2154/2155	2155/2156	2156/2157	2157/2158	2158/2159	2159/2160	2160/2161	2161/2162	2162/2163	2163/2164	2164/2165	2165/2166	2166/2167	2167/2168	2168/2169	2169/2170	2170/2171	2171/2172	2172/2173	2173/2174	2174/2175	2175/2176	2176/2177	2177/2178	2178/2179	2179/2180	2180/2181	2181/2182	2182/2183	2183/2184	2184/2185	2185/2186	2186/2187	2187/2188	2188/2189	2189/2190	2190/2191	2191/2192	2192/2193	2193/2194	2194/2195	2195/2196	2196/2197	2197/2198	2198/2199	2199/2200	2200/2201	2201/2202	2202/2203	2203/2204	2204/2205	2205/2206	2206/2207	2207/2208	2208/2209	2209/2210	2210/2211	2211/2212	2212/2213	2213/2214	2214/2215	2215/2216	2216/2217	2217/2218	2218/2219	2219/2220	2220/2221	2221/2222	2222/2223	2223/2224	2224/2225	2225/2226	2226/2227	2227/2228	2228/2229	2229/2230	2230/2231	2231/2232	2232/2233	2233/2234	2234/2235	2235/2236	2236/2237	2237/2238	2238/2239	2239/2240	2240/2241	2241/2242	2242/2243	2243/2244	2244/2245	2245/2246	2246/2247	2247/2248	2248/2249	2249/2250	2250/2251	2251/2252	2252/2253	2253/2254</
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IN THE SPECIFICATION:

A CROSS-REFERENCE paragraph is added at Page 1.

IN THE CLAIMS:

Original Claims 18-25 have been canceled.

New Claims 18-40 are added.

CHEWING GUM COMPOSITIONS

5

BACKGROUND OF THE INVENTION

10 The present invention relates to chewing gum compositions containing polymeric surface active agents, including polyphosphates. These polymeric surface active agents may provide novel surface conditioning reaction to oral surfaces such as the teeth and mucosa. This leads to improved cleaning impression. The present invention further relates to compositions wherein the chewing gum has a crunchy texture conferred to it by the polyphosphate particles.

15 Polymeric surface active agents, such as polyphosphates, are known in the oral care art. Although disclosed in chewing gum compositions, these ingredients are most commonly found in dentifrice compositions. Polyphosphates are known to provide an anti-calculus benefit as stated in U.S. Patent 5,094,844, US 4808401 and EP 0333301 issued to Gaffar et al.. Polyphosphates are also known to provide a buffering effect within zinc comprising oral compositions as stated in U.S. Patent 4,170,632 and US 4,170,633 both to Wagenknecht, deceased et al. Other chewing
20 gum patents disclosing a polyphosphate include U.S. patent 5,702,687 issued to Miskewitz and EP0,387,024 issued to McClanahan.

Prior art also exists wherein particulate matter has been incorporated into chewing gum compositions such that the resultant product does have a somewhat "crunchy" texture. For example chewing gums with a "crunchy" exterior coating have been previously disclosed such as
25 the hard sugar coated gums disclosed in US 4,486,511 and US 4,792,453 and gums with surface printed solid particles disclosed in US 3,962,463. Such disclosures are limited to a "crunchy" exterior surface of the gum and thus do not provide an overall texture sensation. Furthermore, confectionery gums wherein sugars and sugar substitutes (such as isomalt, candy and the like), sometimes in conjunction with freeze dried food stuffs, are distributed throughout the body of the
30 gum for the purpose, at least in part, of providing a "crunchy" texture are also known (FR 2,748,902; GB 950,811; EP 017,691; US 5,958,472, and US 5,017,385). Whilst these latter disclosures do provide useful advances in conferring a "crunchy" sensation to the gum they do so by the use of food stuffs and not by use of the oral care active itself.

Surprisingly, research has now revealed additional benefits of chewing gums containing
35 polymeric surface active agents, particularly when the polymeric surface active agent is a polyphosphate, even more particularly a particulate polyphosphate. These new benefits are related to effects on the surface chemical characteristics of mucosal and tooth surfaces which provide remarkable cleaning impression and positive mouth feel characteristics for extended

periods of time during and following use. These effects have now been shown to be correlated to effects on oral surface energy characteristics including modification of surface hydrophilic and hydrophobic properties. Additionally, when certain polyphosphates, particularly of a particulate nature, are incorporated within the gum they can confer a "crunchy" texture to the product which lasts throughout the initial minutes of mastication and which reinforces for the consumer the oral care benefit of the product. Furthermore, due to the soluble nature of the polyphosphate materials the "crunchy" texture disappears over time leaving no gritty residue.

The surface conditioning effects can be measured using several different methods. The surface conditioning effects on a subject's teeth and oral mucosa can be measured in vivo. These measurements include consumer responses on questions concerning clean teeth and smooth teeth. Other in vivo measurements include the water contact angle on the tooth surface and on the mucosa surfaces. The surface conditioning effects can also be measured in considerable detail through in vitro methods. In vitro methods are made over time to measure surface free energies and pellicle film thickness and composition.

It has also been found that the polymeric surface active agent can help to reduce the astringency of a metallic ion. Additionally, this reduction in astringency can occur without significantly reducing the efficacy of the metallic ion and without significantly reducing the efficacy and the surface conditioning effects of the polymeric surface active agent.

It is an object of the present invention to provide chewing gum compositions containing polymeric surface active agents which provide improved intraoral cleaning impression and smooth tooth surface impression derived from the chemical control of tooth and mucosal surface energy characteristics.

It is an object of the present invention to provide chewing gum compositions comprising polymeric surface active agents, cationic material, and/or orally active metallic ions.

It is also an object of the present invention to provide chewing gum compositions with reduced astringency, but wherein the efficacy of the chewing gum is not significantly reduced.

It is a further object of this invention to provide a chewing gum which has a "crunchy" texture during the initial minutes of mastication disappearing over time to leave no gritty residue and wherein this "crunchy" texture is provided by a polyphosphate.

These and other objects of the present invention will become readily apparent from the detailed description which follows.

All percentages and ratios used herein are by weight of the specific chewing gum composition, unless otherwise specified. All measurements are made at 25° C, unless otherwise specified.

SUMMARY OF THE INVENTION

A first aspect of this invention relates to a chewing gum composition comprising a polymeric surface active agent. The chewing gum composition may also contain a cationic material and/or an orally active metallic ion. The chewing gum composition will provide surface

conditioning effects on a subject's teeth and/or oral mucosa. The surface conditioning effects can be measured through in vitro or in vivo testing. The in vitro testing shows a total surface energy and/or a lewis base score to increase immediately after treatment with the chewing gum and then decrease over time. The in vivo testing shows a water contact angle of the oral mucosa to decrease after treatment with the chewing gum composition and/or a significantly higher smooth teeth feel relative to other chewing gum compositions. The present invention also relates to methods of providing surface conditioning effects to a subject comprising administering to the subject a chewing gum comprising a polymeric surface active agent. The present invention also relates to methods of reducing astringency of a chewing gum containing a metallic ion without significantly reducing the efficacy of the metallic ion.

According to a second aspect this invention relates to a chewing gum composition which has a crunchy texture wherein the crunchy texture is conferred to the gum by the inclusion of particulate polyphosphate material within the composition. The "crunchy" texture can be attained when the polyphosphate material used has a particle size of between 100 μ m and 2000 μ m. Furthermore, by ensuring that the polyphosphate is at least sparingly soluble the "crunch" will slowly disappear to leave a non gritty gum.

DETAILED DESCRIPTION OF THE INVENTION

The chewing gum compositions of the present invention may be in the form of a conventional chewing gum or any other product form which is suitable for chewing. Suitable physical forms include sticks, dragees, chiclets, and batons. The chewing gum may also be a digestible or dissolvable gum suitable for chewing. A chewing gum is typically retained in the oral cavity for a time sufficient to allow ingredients released to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity.

The term "carrier materials" as used herein means any safe and effective additional chewing gum components used in the chewing gum compositions of the present invention. Such materials include abrasive polishing materials, elastomers, resins, plasticisers, fats, solvents, waxes, emulsifiers, softeners, bulking agents, sweeteners, absorbents, orally active metallic ions, cationic material, fluoride ion sources, additional anticalculus agents, antimicrobial agents, buffers, whitening agents, alkali metal bicarbonate salts, thickening materials, humectants, water, surfactants, titanium dioxide, flavoring agents, xylitol, coloring agents, and mixtures thereof.

The present compositions comprise essential components, as well as optional components. The essential and optional components of the compositions of the present invention are described in the following paragraphs.

35 Polymeric Surface Active Agent

The present invention includes a polymeric surface active agent. The agents will provide the surface conditioning effects. These agents may also be tartar control or anticalculus agents

and may also provide stain control and reduction in plaque. The polymeric surface active agents will also provide a clean teeth and longer lasting clean teeth and mouthfeel.

The polymeric surface active agents include any agent which will produce the desired surface conditioning effects. The desired surface conditioning effects include the desorption of adsorbed pellicle proteins and creating a hydrophilic tooth surface immediately after treatment. These surface conditioning effects are measured through in vitro methods over time. The agents will also create several related surface conditioning effects which are measured through in vivo testing done over time. The effects include creating an increased hydrophilic surface on the tooth surface and a hydrophobic surface on the oral mucosa as measured by changed water contact angles. It is thought that these measurements will correlate with consumers noticing a cleaning impression.

The polymeric surface active agents include the phosphorylated polymers, polyelectrolytes, and acrylate polymers. Additional polyelectrolytes include the antibacterial enhancing agents described in U.S. patents 5,032,386 and 5,840,281, both to Gaffar et al. A preferred polymeric agent is polyvinylphosphonic acid. Other suitable polymeric surface active agents include the polymers described in U.S. patents 5,292,501; 5,213,789; 5,093,170; 5,009,882; and 4,939,284; all to Degenhardt et al. and U.S. patent 5,011,913 to Benedict et al. A preferred polymer is diphosphonate modified polyacrylic acid. Polymers with activity must have sufficient surface binding propensity to desorb pellicle proteins and remain affixed to intraoral surfaces. For tooth surfaces, polymers with end or side chain phosphate or phosphonate functions are preferred, although other polymers with mineral binding activity may prove effective depending upon adsorption affinity.

The preferred polymeric surface active agent is a polyphosphate. A polyphosphate is generally understood to consist of two or more phosphate molecules arranged primarily in a linear configuration, although some cyclic derivatives may be present. Although pyrophosphates and tripolyphosphate are a polyphosphates, the polyphosphates desired are those having around four or more phosphate molecules so that one or more internal phosphate groups may be present. The pyrophosphates are discussed separately under anticalculus agents. The inorganic polyphosphate salts desired include tetrapolyphosphate and hexametaphosphate, among others. Polyphosphates larger than tetrapolyphosphate usually occur as amorphous glassy materials. Preferred in this invention are the linear "glassy" polyphosphates having the formula:



wherein X is sodium, potassium, or hydrogen and n averages from about 6 to about 125. For use in the second aspect of this invention it is preferred that the particulate polyphosphate is sodium polyphosphate with an average chain length of from about 10 to about 30, preferably from about 15 to 25, more preferably from about 21 to about 23. Preferred are polyphosphates manufactured by FMC Corporation which are commercially known as Sodaphos ($n \approx 6$), Hexaphos ($n \approx 13$), and Glass H ($n \approx 21$). Hexaphos and Glass H are preferred with Glass H being the most preferred

polyphosphate. These polyphosphates may be used alone or in a combination thereof. The phosphate sources are also described in more detail in Kirk & Othmer, *Encyclopedia of Chemical Technology*, Fourth Edition, Volume 18, Wiley-Interscience Publishers (1996), incorporated herein by reference in its entirety, including all references incorporated into Kirk & Othmer.

5 The amount of polymeric surface agent required is an effective amount to provide the surface conditioning effects and, if desired, according to a second aspect of the invention, to provide a "crunchy" texture. An effective amount of a polymeric surface active agent will typically be from about 0.1% to about 50%, preferably from about 1% to about 35%, more preferably from about 2% to about 25%, and most preferably from about 5% to about 15% by weight of the total
10 chewing gum composition. In addition to creating the surface conditioning effects, the polymeric surface active agent has been found to associate with orally active metallic ions or species whilst maintaining their solubility and efficacy. For example, the polymeric surface active agent may form a complex with stannous fluoride or zinc and still provide the desired tartar control, stain control, and surface conditioning, in addition to not significantly prohibiting the efficacy of the
15 stannous fluoride or zinc. The polymeric surface active agents may enhance the solubility of orally active metallic ions, such as zinc salts and stannous salts. The orally active metallic ions may provide several efficacious benefits to the chewing gum such as reduced gingivitis, plaque, and sensitivity and improved breath. In addition to not significantly reducing the efficacy of an orally active metallic ion, the polymeric surface active agents, particularly sodium polyphosphate,
20 may reduce the amount of astringency created by the orally active metallic ion. This may be due to lower levels of mucosal protein precipitation in the mouth. This can be measured by in vivo testing and sensory scores. The preferred orally active metallic ions are zinc and tin or stannous. The orally active metallic ions are typically present in an amount of from about 0.01% to about 10%, preferably from about 0.05% to about 5%, more preferably from about 0.1% to about 1%, by
25 weight of the chewing gum.

 It may be desirable to have a sustained release of the polymeric surface active agent from the chewing gum. This may be accomplished by incorporating a cationic material whose polymeric surface active agent salt is less soluble in water than the sodium, potassium or hydrogen salts. By adding such cationic material, particularly divalent cationic materials such as
30 calcium, the release rate of the polymeric surface active agent may be tailored to a required profile. The maximum level of cationic material incorporated is one cation per monomer unit forming the polymeric surface active agent. The level of cationic material incorporated is more preferably less than 0.5 cations per monomer unit forming the polymeric surface active agent. By weight percent, the polymeric surface active agent is generally present in at least about two times
35 the cationic material, preferably about four times the cationic material, and more preferably at least about five times the cationic material. For example, the cationic material is typically present in an amount of up to about 10%, preferably from about 0.05% to about 5%, and more preferably from about 0.1% to about 3%, by weight of the chewing gum.

The particulate polyphosphate material preferred for use in the second aspect of the present invention should have a minimum particle size such that they are retained by a 0.1mm mesh, preferably a 0.112mm mesh, more preferably a 0.16mm mesh, even more preferably a 0.18mm mesh and most preferably a 0.2mm mesh wherein the meshes are selected from the DIN 4188 mesh series . Furthermore the solid particulate materials for use in the second aspect of the present invention should have a maximum particle size such that pass through a 2mm mesh, preferably a 1mm mesh, more preferably an 0.8mm mesh, even more preferably a 0.5mm mesh and most preferably a 0.4mm mesh, again wherein the meshes are selected from the DIN 4188 mesh series.

The solubility of the particulate polyphosphate preferred for use in the second aspect of the present invention should be at least 5g per 100ml at 25°C, preferably of at least 8g, more preferably at least 10g, even preferably at least 15g per 100ml at 25°C. Thus the solid particulate should be "sparingly soluble", or preferably more soluble, wherein the term is defined as in the British Pharmacopoeia, 1999, Volume 1. Whilst there is no limit on the upper solubility of the polyphosphate it is preferred that it is not freely soluble in water otherwise it will dissolve too rapidly for a crunch to be experienced.

It is preferred that particulate polyphosphate materials for use in the second aspect of the present invention have hardness of greater than 1, preferably of 2 or greater, on the Mohs hardness scale. It is also preferred that the particulate polyphosphate materials for use in the second aspect of this invention are distributed evenly throughout the gum base. Additionally it is also preferred that, according to the second aspect of this invention, that the weight ratio of gum to particulate polyphosphate is in the range from about 10:1 to about 1:10, preferably from about 5:1 to about 1:5, more preferably from about 5:1 to about 1:1.

Additional chewing gum components

In preparing the present chewing gum compositions, it is desirable to add one or more additional chewing gum components. Such materials are well known in the art and are readily chosen by one skilled in the art based on the physical and aesthetic properties desired for the chewing gum compositions being prepared. These carriers may be included at levels which do not interfere or prohibit the surface conditioning. The amount of polymeric surface active agent may be increased to account for the additional components. The additional chewing gum components typically comprise from about 30% to about 99%, preferably from about 40% to about 98%, and more preferably from about 70% to about 95%, by weight of the chewing gum composition.

Additional chewing gum components include carrier materials. The carrier materials are water insoluble materials which are typically not released in the mouth and water soluble materials which are released in the mouth. Water insoluble materials are typically used to form a chewing gum base.

An abrasive polishing material may be included in the chewing gum compositions. The abrasive polishing material contemplated for use in the compositions of the present invention can be any material which does not excessively abrade dentin. The abrasive polishing material should be formulated in the chewing gum composition so that it does not compromise the stability of any ingredients. Typical abrasive polishing materials include silica gels and precipitates; aluminas; water soluble phosphates (including orthophosphates, polymetaphosphates, and pyrophosphates); and mixtures thereof. Specific examples include dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, beta calcium pyrophosphate, calcium carbonate, and resinous abrasive materials such as particulate condensation products of urea and formaldehyde. Mixtures of abrasives may also be used. The abrasive in the chewing gum compositions is generally from about 1% to about 70% and preferably from about 5% to about 50%, by weight of the chewing gum composition.

Another ingredient of the chewing gum composition is an elastomer or elastomer mixture. The elastomers useful in the present composition include styrene-butadiene rubber (SBR) and other elastomeric materials generally known in the art. Illustrative elastomers include SBR, synthetic gums or elastomers such as polyisobutylene and isobutylene-isoprene copolymers; natural gums or elastomers such as chicle, natural rubber, jelutong, balata, guttapercha, lechi caspi, sorva and mixtures thereof. The elastomer or elastomer mixture is generally present in an amount of from 2% to about 30% and preferably from about 5% to about 25% by weight. When the total amount of elastomer is below 2% the base composition lacks elasticity, chewing texture, and cohesiveness whereas at amounts above about 30% the formulation is hard, rubbery and maintains a tight chew.

An optional but desirable ingredient of the chewing gum composition is a resin. The resin serves to plasticise the gum base. Suitable resins for use herein include polyvinyl acetate (PVA) and terpene resins, including polyterpene and polymers of alpha-pinene or beta-pinene, and mixtures thereof. The resin can conveniently be used at a level of from about 3% to about 25%, preferably from about 5% to about 20% by weight of the gum composition.

In addition to the resin component, the gum base compositions of the present invention preferably comprise a plasticiser in an amount up to about 10%, preferably from about 0.1% to about 3% by weight of the gum composition. Suitable plasticisers include glyceryl triacetate, acetylated monoglyceride, glyceryl tributyrate, ethyl laurate, ethyl acetoacetate, diethyl tartrate, ethyl or butyl lactates, diethyl malate, ethyl oleate, castor oil, succinylated monoglycerides or mixtures thereof. Glyceryl triacetate and acetylated monoglyceride are preferred.

Various fats can also be included in the chewing gum compositions of the present invention. Preferred fats include the hydrogenated vegetable oils such as hydrogenated palm oil, hydrogenated soybean oil, hydrogenated cotton seed oil and various other hydrogenated

vegetable oils and mixtures thereof. The fats can suitably be used at a level up to about 20%, preferably from about 1% to about 10% by weight of the chewing gum composition.

A further desirable ingredient of the chewing gum base composition is an elastomer solvent. The elastomer solvent aids in softening the elastomer component. Such elastomer solvents include methyl, glycerol or pentaerythritol esters of rosins or modified rosins, such as hydrogenated, dimerized or polymerised rosins or mixtures thereof. Examples of elastomer solvents suitable for use herein include the pentaerythritol ester of partially hydrogenated wood rosin, pentaerythritol ester of wood rosin, glycerol ester of partially dimerized rosin, glycerol ester of polymerised rosin, glycerol ester of tall oil, wood or gum rosin, glycerol ester of partially hydrogenated rosin, methyl ester of partially hydrogenated rosin, and mixtures thereof. The elastomer solvent can be employed in an amount ranging from about 2% to about 50%, preferably from about 10% to about 35% by weight of the chewing gum.

The gum base compositions can also include one or more waxes. Suitable waxes include paraffin wax; microcrystalline wax; Fischer-Tropsch paraffin; natural waxes such as candellilla, carnauba and beeswax; polyolefin waxes such as polyethylene wax; and mixtures thereof. The waxes can be present in levels up to about 25%, preferably from about 5% to about 20% by weight of the gum composition.

The chewing gum also preferably includes an emulsifier. Suitable emulsifiers include glycerol monostearate, lecithin, fatty acid monoglycerides, diglycerides, propylene glycol monostearate and mixtures thereof. The emulsifier is employed in amounts up to about 10% and preferably from about 2% to about 6% by weight of the chewing gum.

A variety of softeners can also be employed in the chewing gum compositions of the present invention. Suitable softeners include fatty materials such as lanolin, stearic acid, sodium stearate and potassium stearate; polyhydric alcohols such as glycerine, propylene glycol, and the like; and mixtures thereof. The softeners can suitably be used at a total level of up to about 30%, preferably from about 0.1% to about 10% by weight of the chewing gum. In a preferred embodiment, the chewing gum composition comprises a fatty softener selected from stearic acid, sodium stearate, potassium stearate and mixtures thereof in an amount of from about 0.1% to about 10% by weight of the chewing gum. Preferably, the fatty softener is stearic acid. The gum base composition may further comprise a polyhydric alcohol. If present, the polyhydric alcohol is present in an amount of from about 0.5% to about 25%, more preferably from about 1% to about 10% by weight of the chewing gum. Such materials, when incorporated into the gum base, assist in modifying the texture and consistency properties. In particular, they help to soften the chew and to maintain chew softness over an extended period of time.

Bulking agents, such as fillers, can also be employed in the chewing gum. Suitable fillers and bulking agents are generally non-abrasive, preferably with an average particle size less than 5 μm , more preferably less than 3 μm and especially less than 1 μm . Illustrative bulking agents

include calcium carbonate or ground limestone, talc, aluminium hydroxide, alumina, aluminium silicates, dicalcium phosphate and mixtures thereof. Where present, the filler can be used in levels up to about 50%, preferably up to about 30%, most preferably from up to about 10% by weight of the chewing gum.

- 5 Suitable bulk sweeteners are monosaccharides, disaccharides, and polysaccharides such as xylose, ribose, glucose, mannose, galactose, fructose, dextrose, sucrose, sugar maltose, fructo oligo saccharide syrups, partially hydrolysed starch, or corn syrup solids. Preferred sweetening agents are sugar alcohols such as sorbitol, xylitol, mannitol, maltitol, isomalt, hydrogenated starch hydrolysate, inulin, and other non-cariogenic edible polyols such as glycerin and erythritol and
10 mixtures thereof.

- In general, the amount of sweetener will vary with the sweetener used and desired amount of sweetener selected for a particular chewing gum. This amount will normally vary from about 0.01% when using a high intensity sweetener to about 80% by weight of the chewing gum composition when using an easily extractable bulk sweetener. The bulk sweeteners described
15 above, are preferably used in amounts of about 10% to about 80% by weight and most preferably about 30% to about 70% by weight. These amounts are ordinarily necessary to achieve a desired level of sweetness independent from the flavor level achieved from the flavoring agents.

- In preferred embodiments, the chewing gum composition further comprises a high intensity sweetener. Suitable high intensity sweeteners include: dipeptide based sweeteners such as L-aspartyl-L-phenylalanine methyl ester (Aspartame) and equivalents described in U.S. Pat.
20 No. 3,492,131, L- α -aspartyl-N-(2,2,4,4-tetramethyl-3-thietanyl)-D-alaninamide hydrate (Alitame) and the like; the soluble saccharin salts, i.e., sodium or calcium saccharin salts; cyclamate salts, acesulfame-K and the like; the free acid form of saccharin; chlorinated derivatives of sucrose such as chlorodeoxysucrose and the like; and protein based sweeteners, such as Thaumatin (talin).
25 The high intensity sweeteners described can be added in amounts of from about 0.01% to about 2.0% and most preferably from about 0.05% to about 0.5% by weight of the chewing gum composition. Using a high intensity sweetener within the gum base may prolong the flavor of the finished gum composition during chewing.

- The chewing gum can also include colorants and pigments, such as titanium dioxide. In
30 general, the gum can contain up to about 2% of pigment and / or colorant. Anti-oxidants can also be included in the gum, at a level of up to about 0.5%. Suitable anti-oxidants are butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate, ascorbic acid and tocopherols.

- Flavoring agents well known in the chewing gum art can be added to the chewing gum compositions of the invention. These flavoring agents can be chosen from synthetic flavoring
35 liquid and/or oils derived from plants leaves, flowers, fruits and so forth, and combinations thereof. Representative flavoring liquids include: spearmint oil, cinnamon oil, oil of wintergreen (methylsalicylate) and peppermint oils. Also useful are artificial, natural or synthetic fruit flavors

such as citrus oil including lemon, orange, banana, grape, lime, apricot and grapefruit and fruit essences including apple, strawberry, cherry, orange, pineapple and so forth; bean and nut derived flavors such as coffee, cocoa, cola, peanut, almond and so forth. Additionally, flavor adsorbed onto a hydrophilic matrix may be included e.g. "spray-dried" flavors. Furthermore
5 encapsulated flavors may be included. Also included in the term flavorant are sensates and coolants. Preferred coolants include MGA, Physcool, WS-3, WS-23, TK-10, and combinations thereof.

The amount of flavorant employed is normally a matter of preference subject to such factors as flavor type, base type and strength desired. In general, amounts up to about 4% by
10 weight and preferably about 0.05% to about 3.0% by weight of the chewing gum composition are usable with amounts of about 0.8% to about 2.5% being preferred.

Water employed in the preparation of commercially suitable chewing gum compositions should preferably be of low ion content and free of organic impurities. Water will generally comprise less than about 10%, preferably from about 0.01% to about 5%, and more preferably
15 from about 0.1% to about 3%, by weight of the composition herein. The amounts of water include the free water which is added plus that which is introduced with other materials, such as with sorbitol, silica, and solutions.

The present invention may also include other agents, such as antimicrobial agents. The chewing gum composition may include an orally active metallic ion as an antimicrobial agent,
20 particularly salts of zinc, tin and silver and copper.

Other antimicrobial agents include the water insoluble non-cationic antimicrobial agents such as halogenated diphenyl ethers, phenolic compounds including phenol and its homologs, mono and poly-alkyl and aromatic halophenols, resorcinol and its derivatives, bisphenolic compounds and halogenated salicylanilides, benzoic esters, and halogenated carbanilides. The
25 water soluble antimicrobials include quaternary ammonium salts and bis-biquanide salts, among others. Triclosan monophosphate is an additional water soluble antimicrobial agent. The quaternary ammonium agents include those in which one or two of the substitutes on the quaternary nitrogen has a carbon chain length (typically alkyl group) from about 8 to about 20, typically from about 10 to about 18 carbon atoms while the remaining substitutes (typically alkyl or
30 benzyl group) have a lower number of carbon atoms, such as from about 1 to about 7 carbon atoms, typically methyl or ethyl groups. Dodecyl trimethyl ammonium bromide, tetradecylpyridinium chloride, domiphen bromide, N-tetradecyl-4-ethyl pyridinium chloride, dodecyl dimethyl (2-phenoxyethyl) ammonium bromide, benzyl dimethylstearyl ammonium chloride, cetyl pyridinium chloride, cetyl pyridinium saccharinate, quaternized 5-amino-1,3-bis(2-ethyl-hexyl)-5-
35 methyl hexa hydropyrimidine, benzalkonium chloride, benzethonium chloride and methyl benzethonium chloride are exemplary of typical quaternary ammonium antibacterial agents. Other compounds are bis[4-(R-amino)-1-pyridinium] alkanes as disclosed in U.S. Patent 4,206,215, issued June 3, 1980, to Bailey, incorporated herein by reference. Other antimicrobials such as

copper bisglycinate, copper glycinate, zinc citrate, zinc citrate-maleate, zinc lactate, hexetidine, hexamidine, furanones, and phalimido-peroxycaproic acid may also be included. Also useful are enzymes, including endoglycosidase, papain, dextranase, mutanase, and mixtures thereof. Such agents are disclosed in U.S. Patent 2,946,725, Jul. 26, 1960, to Norris et al. and in U.S. Patent 4,051,234, September 27, 1977 to Gieske et al., incorporated herein by reference. Specific antimicrobial agents include chlorhexidine, triclosan and its derivatives including triclosan monophosphate, triclosan diphosphate, and phenolated triclosan and flavor oils such as thymol, geraniol, eugenol, and biosol. Triclosan and other agents of this type are disclosed in Parran, Jr. et al., U.S. Patent 5,015,466, issued May 14, 1991, and U.S. Patent 4,894,220, Jan. 16, 1990 to Nabi et al., incorporated herein by reference. These agents may be present at levels of from about 0.01% to about 10%, preferably from about 0.05% to about 5%, and more preferably from about 0.1% to about 2%, by weight of the chewing gum composition.

Optional agents that may be used in combination with the polymeric surface active agent include materials known to be effective in reducing calcium phosphate mineral deposition related to calculus formation. Pyrophosphate salts may be used in the present invention as anticalculus agents or as buffering agents, as long of the surface conditioning effects of the polymeric surface active agent is not eliminated. The amount of pyrophosphate salt useful in making these compositions is any tartar control effective amount, and is generally from about 1.5% to about 15%, preferably from about 2% to about 10%, and most preferably from about 2.5% to about 8%, by weight of the chewing gum composition. Other agents included are synthetic anionic polymers [including polyacrylates and copolymers of maleic anhydride or acid and methyl vinyl ether (e.g., Gantrez), as described, for example, in U.S. Patent 4,627,977, to Gaffar et al., the disclosure of which is incorporated herein by reference in its entirety; as well as, e.g., polyamino propoane sulfonic acid (AMPS)], zinc citrate trihydrate, diphosphonates (e.g., EHDP; AHP), polypeptides (such as polyaspartic and polyglutamic acids), and mixtures thereof.

The present invention may also include buffering agents to adjust the pH of the chewing gum and may help to stabilize the polymeric surface active agent. Other potential ingredients include a fluoride ion source. An alkali metal bicarbonate salt, surfactants, whitening agents such as peroxide or percarbonate, coloring agents, xylitol, thickening materials, binders, humectants, absorbents such as activated carbon, silica absorbents, cyclodextrins, and zeolites and combinations thereof, may also be included in the chewing gum composition.

The chewing gum composition may be in the form of a chiclet or other form that contains a outer coating or shell around the central portion or gum base of the chewing gum. The outer coating may be hard or crunchy. Typically, the outer coating will be comprised of about sorbitol, malitol, xylitol, isomalt, and other crystallisable polyols. The outer coating may also contain small amounts of water and gum arabic. A polyol coating can be further coated with wax. The present invention may have the polymeric surface active agent present in the chewing gum base, the outer coating, or both.

- It may be desirable to have a rapid release of the polymeric surface active agent from the chewing gum. This may be accomplished by incorporating some or all of the polymeric surface active agent into the outer coating. To further increase the rate of release of the polymeric surface active agent from the outer coating, the particles are processed in a manner to result in a microporous sized porosity.

Method of Treatment

- The present invention relates to methods for providing surface conditioning effects. The present invention also relates to methods of providing clean mouth and tooth feel, smooth teeth feel, and longer lasting clean or smooth tooth feel. Additional efficacy, such as reduced gingivitis, plaque, calculus, and sensitivity, and improved breath may also occur depending upon the composition of the chewing gum. The benefits of these compositions may increase over time when the composition is repeatedly used.

- The method of treatment herein comprises contacting a subject's dental enamel surfaces and mucosa in the mouth with the chewing gum compositions according to the present invention. The method of treatment will typically be by chewing the gum. The subject may be any person or lower animal whose tooth surface contact the chewing gum composition.

Examples & Method of Manufacturing

- The following examples further describe and demonstrate embodiments within the scope of the present invention. These examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention as many variations thereof are possible without departing from the spirit and scope.

Material Name (INCI)	A	B	C Core	Coatin g	D Core	Coating
Sorbitol	25.850	18.350	33.350		33.350	
Xylitol	16.700	16.700	16.700		16.700	
Gum base (e.g. Prestige-PL, Cafosa)	28.000	28.000	28.000		28.000	
Sodium polyphosphate, n=21; Glass H (FMC)	7.500	15.000	0.000	37.500	0.000	
Glass H (microporous sized)						37.500
Hydrogenated starch hydrolisate (85% solids)	8.000	8.000	8.000		8.000	
Glycerin	7.000	7.000	7.000		7.000	
Mannitol	5.000	5.000	5.000		5.000	
Maltitol				62.250		62.250
Ethyl cellulose (Ethocell, Dow)						

Corning)						
Zinc lactate dihydrate						
Sodium polyphosphate, n=6; Sodaphos (FMC)						
Sodium polyphosphate, n=13; Hexaphos (FMC)						
Poloxamer 407						
Flavor	1.600	1.600	1.600	0.250	1.600	0.250
Aspartame	0.200	0.200	0.200		0.200	
Spray dried flavor	0.150	0.150	0.150		0.150	
TOTAL	100.00	100.00	100.000	100.00	100.000	100.000
	0	0		0		
% OF TOTAL COMPOSITION	100.00	100.00	80.000	20.000	80.000	20.000
	0	0				

Material Name (INCI)	E	F	G	H	I	J	K
Sorbitol	15.850	25.123	18.350	23.350	23.850	23.850	24.719
Xylitol	16.700	16.700	16.700	16.700	16.700	16.700	16.700
Gum base (e.g. Prestige-PL, Cafosa)	28.000	28.000	28.000	28.000	28.000	28.000	28.000
Sodium polyphosphate, n=21; Glass H (FMC)	7.500	7.500			7.500	7.500	7.500
Hydrogenated starch hydrolysate (85% solids)	8.000	8.000	8.000	8.000	8.000		8.000
Glycerin	7.000	7.000	7.000	7.000	7.000	7.000	7.000
Mannitol	5.000	5.000	5.000	5.000	5.000	5.000	5.000
Maltitol						8.000	
Ethyl cellulose (Ethocell, Dow Corning)	10.000						
Zinc lactate dihydrate		0.727					
Sodium polyphosphate, n=6; Sodaphos (FMC)			15.000				
Sodium polyphosphate, n=13; Hexaphos (FMC)				10.000			
Poloxamer 407					2.000	2.000	
Flavor	1.600	1.600	1.600	1.600	1.600	1.600	1.600

Aspartame	0.200	0.200	0.200	0.200	0.200	0.200	0.200
Spray dried flavor	0.150	0.150	0.150	0.150	0.150	0.150	0.150
Calcium chloride							0.754
TOTAL	100.000	100.00	100.00	100.00	100.00	100.00	100.00
				0	0	0	0
% OF TOTAL COMPOSITION	100.000	100.00	100.00	100.00	100.00	100.00	100.00
				0	0	0	0

Making Instructions**Products A, B**

- Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes. Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol, Glass-H and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

10 **Products C, D**

- Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes. Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes. Store for ~1 week at 15-20°C, 30-60% RH (conditioning). Tumble chewing gums in coater-drier with maltitol solution and Glass-H. Maintain tumbling until surface is dry.

20 **Product E**

- Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes. Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol, Glass-H in encapsulated ethyl cellulose and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

Product F

Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add

mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes. Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol, Glass-H, zinc lactate, and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

5 Product G, H

Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes.

- 10 Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol, sodaphos, hexaphos, and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

Product I

Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes. Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol, Glass-H, Poloxamer 407, and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

Product J

- 20 Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 7 minutes. Add 50% sorbitol and mix for 3 minutes. Add second 50% of xylitol, Glass-H and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

25 Product K

Heat gum base to ~45°C to soften. Maintain mixer vessel cavity at ~45°C during entire mixing process. Add gum base to mixing cavity of double sigma blade mixer and mix for 5 minutes. Add mannitol and spray-dried menthol. Mix for 2 minutes. Add glycerin and mix for 2 minutes. Add 50% of xylitol and mix for 2 minutes. Add hydrogenated starch hydrolysate and mix for 5 minutes.

- 30 Add 50% sorbitol, calcium chloride and mix for 3 minutes. Add second 50% of xylitol, Glass-H and aspartame and mix for 3 minutes. Add flavor and mix for 3 minutes.

CLAIMS:

- 5
1. A chewing gum composition comprising a polymeric surface active agent wherein the chewing gum provides surface conditioning effects on a subject's teeth which is measured by in vitro testing showing total surface energy to increase immediately after treatment with the chewing gum and then decrease over time.
 2. A chewing gum composition comprising a polymeric surface active agent wherein the chewing gum provides surface conditioning effects on a subject's teeth which is measured by in vitro testing showing lewis base score to increase immediately after treatment with the chewing gum and then decrease over time.
 3. A chewing gum composition comprising a polymeric surface active agent wherein the chewing gum provides surface conditioning effects on a subject's oral mucosa which is measured by in vivo testing showing a water contact angle to decrease after treatment with the chewing gum.
 4. A chewing gum composition comprising a polymeric surface active agent wherein the chewing gum provides surface conditioning effects on a subject's teeth which is measured by in vivo testing showing a significantly higher smooth teeth feel relative to other chewing gums.
 5. A method of providing surface conditioning effects to a subject comprising administering to the subject a chewing gum composition comprising a polymeric surface active agent.
 6. A chewing gum composition comprising:
 - a. from about 0.1% to about 50% of a polymeric surface active agent;
 - b. up to about 10% of water; and
 - c. from about 40% to about 99% of carrier materials.
 7. The chewing gum composition according to Claim 6 wherein the chewing gum has an outer coating.
 8. The chewing gum composition according to Claim 6 where the chewing gum further comprises a cationic material.

9. The chewing gum composition according to Claim 8 wherein the cationic material controls the release rate of the polymeric surface active agent.
10. The chewing gum composition according to Claim 8 wherein the cationic material is calcium.
11. The chewing gum composition according to Claim 6 wherein the polymeric surface active agent is a glassy polyphosphate.
12. The chewing gum composition according to Claim 11 wherein the glassy polyphosphate is Glass H.
13. The chewing gum composition according to Claim 6 wherein the chewing gum further comprises an orally active metallic ion.
14. The chewing gum composition according to Claim 13 wherein the astringency of the chewing is reduced by the polymeric surface active agent.
- 5 15. The chewing gum composition according to Claim 14 wherein the efficacy of the orally active metallic ion is not significantly reduced by the polymeric surface active agent.
16. A method of reducing astringency of a chewing gum composition containing an orally active metallic ion comprising administering to the subject the chewing gum comprising:
 - a. from about 0.1% to about 50% of a polymeric surface active agent;
 - b. from about 0.01% to about 10% of an orally active metallic ion;
 - 5 c. up to about 10% of water; and
 - d. from about 30% to about 99% of carrier materials;

wherein the efficacy of the orally active metallic ion is not significantly reduced by the polymeric surface active agent.
17. A chewing gum comprising:
 - 10 (a) from about 0.1% to about 50% of a particulate polyphosphate wherein the particulate polyphosphate:
 - (i) has a particle size such that it passes through a 2mm mesh and is retained by a 0.1mm;
 - (ii) has an aqueous solubility of at least 5g per 100ml at 25°C;

- 15 (b) greater than about 10% gum base comprising one or more elastomers, resins or waxes and mixtures thereof.
18. A composition according to Claim 17 which comprises from about 0.5% to about 30%, preferably from about 1% to about 15%, more preferably from about 5% to about 12%, by weight, of particulate polyphosphate.
- 20 19. A composition according to any of Claims 17 to 18 wherein the particulate polyphosphate has a particle size such that it passes through a 1mm mesh, preferably a 0.8mm mesh, more preferably 0.5mm mesh and even more preferably a 0.4mm mesh.
20. A composition according to any of Claims 17 to 19 wherein the particulate polyphosphate has a particle size such that it is retained by a 0.112mm mesh, preferably a 0.16mm mesh, more preferably a 0.18mm mesh and even more preferably a 0.2mm mesh.
- 25 21. A composition according to any of Claims 17 to 20 wherein the particulate polyphosphate is sodium polyphosphate with an average chain length of from about 10 to about 30, preferably from about 15 to 25, more preferably from about 21 to about 23.
- 30 22. A composition according to any of Claims 17 to 21 wherein the particulate polyphosphate has an aqueous solubility of at least 8g, preferably at least 10g, more preferably at least 15g per 100ml at 25°C.
23. A composition according to any of Claims 17 to 22 wherein the particulate polyphosphate has a hardness of greater than 1, preferably 2, or greater, when measured using the Mohs hardness scale.
- 35 24. A composition according to any of Claims 17 to 23 wherein the particulate polyphosphate is dispersed throughout the chewing gum composition.
25. A composition according to any of Claims 17 to 24 wherein the weight ratio of gum to particulate polyphosphate is in the range from about 10:1 to about 1:10, preferably from about 5:1 to about 1:5, more preferably from about 5:1 to about 1:1.

DECLARATION COMBINED WITH POWER OF ATTORNEY

Page 1 of 2

Attorney Docket No. 7943M

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CHEWING GUM COMPOSITIONS

the specification of which

☐ is attached hereto.

☒ was filed on June 22, 2000 as

PCT International Application Number US 00/17177.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations §1.56.

I hereby claim foreign priority benefits under Title 35 United States Code §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)Priority Claimed

(Number)

(Country)

(Day/Month/Year Filed)

☐☐

Yes

No

(Number)

(Country)

(Day/Month/Year Filed)

☐☐

Yes

No

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

60/165,351November 12, 199960/180,352February 4, 2000

Application Serial No.

Filing Date

Application Serial No.

Filing Date

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (If applicable)

As named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

<u>Atty Name</u>	<u>Atty Reg Number.</u>	<u>Associate Power of Attorney Attached</u>
Emelyn L. Hiland	<u>41,501</u>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Betty J. Zea	<u>36,069</u>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Karen F. Clark	<u>32,974</u>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
T. David Reed	<u>32,931</u>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Timothy B. Guffey	<u>41,048</u>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

SEND CORRESPONDENCE TO:

Emelyn L. Hiland, Health Care Research Center (Box 1050)

The Procter & Gamble Company

(513) 622-3236

Name

Phone No.

P.O. Box 8006

Mason

Ohio

45040-8006

Street

City

State

Zip Code

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first joint inventor, if any Trevor Neil Day

Inventor's signature Trevor Neil Day Date 9th April '01

Residence 19, Balmoral Gardens, Windsor SL4 3SG, England ENG

Citizenship England

Post Office Address 19, Balmoral Gardens, Windsor SL4 3SG, England

Full name of second joint inventor Donald James White, Jr.

Inventor's signature Donald James White Jr. Date 4-3-01

Residence 5690 Bordeaux Way, Fairfield, OH 45014 OH

Citizenship USA

Post Office Address 5690 Bordeaux Way, Fairfield, OH 45014

Full name of third joint inventor, if any

Inventor's signature

Date

Residence

Citizenship

Post Office Address

Full name of fourth joint inventor, if any

Inventor's signature

Date

Residence

Citizenship

Post Office Address

Full name of fifth joint inventor, if any

Inventor's signature

Date

Residence

Citizenship

Post Office Address

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the matter of :
 :
 :
 U.S. National Phase Entry :
 Under 35 USC 371 from :
 the International Application of :
 DAY, Trevor et al :
 Int'l Application No. PCT/US00/17177 :
 Filed in the RO/US on 22 June 2000 :
 Entitled: *Chewing Gum Compositions* :

ASSOCIATE POWER OF ATTORNEY

Assistant Commissioner for Patents
Box PCT
Washington, D.C. 20231

Dear Sir:

You are requested to recognize Emelyn L. Hiland (Registration No. 41,501); Betty J. Zea (Registration No. 36,069) and Karen F. Clark (Registration No. 32,974) as Associate Attorney to prosecute this application, to make alterations and amendments therein, and to transact all business in the Patent Office connected with the application or with the patent granted thereupon.

Please address all future communications to:

Emelyn L. Hiland
The Procter & Gamble Company
Health Care Research Center
8340 Mason-Montgomery Road
Mason, OH 45040

Respectfully submitted for Applicants,

By



T. David Reed
Agent for Applicant
Registration No. 32,931

24 April 2001
Cincinnati, Ohio
(513) 627-7025/FAX 627-6333